

TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference GRA3142PCT	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/EP2004/014146	International filing date (<i>day/month/year</i>) 13.12.2004	Priority date (<i>day/month/year</i>) 12.12.2003
International Patent Classification (IPC) or national classification and IPC A61K9/70		
Applicant LTS LOHMANN THERAPIE-SYSTEME AG		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising: a. <input checked="" type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of <u>4</u> sheets, as follows: <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input checked="" type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 4-27 _____ as originally filed/furnished
- pages* 1-3 _____ received by this Authority on 14.09.2005 with letter of 12.09.2005
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. 2-15 _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* 1 _____ received by this Authority on 14.09.2005 with letter of 12.09.2005
- nos.* _____ received by this Authority on _____
- ☒ the drawings:
- sheets 1/3-3/3 _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☒ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☒ the description, pages 1-3 _____
- ☒ the claims, nos. 1 _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1.	Statement		
	Novelty (N)	Claims <u>1-15</u>	YES
		Claims _____	NO
	Inventive step (IS)	Claims _____	YES
		Claims <u>1-15</u>	NO
	Industrial applicability (IA)	Claims <u>1-15</u>	YES
		Claims _____	NO
2.	Citations and explanations (Rule 70.7)		
1.	See supplemental sheet: continuation of Box I.		
2.	<p>In these proceedings, reference is made to documents cited in the international search report. The documents are numbered D1 to D5 according to the order in which they are cited in the search report. The cited passages of the respective documents, in particular, will be taken into account.</p>		
3.	<p>Novelty (PCT Article 33(2))</p> <p>The subject matter of claims 1 to 15 is considered to be novel over the cited prior art.</p> <p>Claim 1 differs from the disclosure in D1 to D3 by the addition of glycerol as a plasticizer.</p>		
4.	<p>Inventive step (PCT Article 33(3))</p> <p>The problem addressed by the application is that of providing a film-forming administration form for the topical administration of at least one active substance, which administration form is easier to use, in particular, with regard to improved application thereof.</p>		

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
	<p>This problem is solved by a film-forming administration form according to claim 1 comprising glycerol as a plasticizer.</p> <p>Film-forming administration forms comprising cross-linked hydrophilic polymers, in particular, HPMC crosslinked with tannin, are already known from the prior art (D1 to D3). D1 to D3 do not, however, disclose the addition of glycerol as a plasticizer.</p> <p>However, a person skilled in the art is familiar with glycerol as an additive functioning as a plasticizer to polysaccharide films, in particular, HPMC films, from D4 and D5.</p> <p>It seems likely that a person skilled in the art would have taken in particular D5 into account because this document deals in general with the mechanical and water vapor transmission properties of polysaccharide films.</p> <p>D5 (page 1203, right-hand column, lines 43-46) describes that HPMC films are effectively plasticized with glycerol and that with 30% glycerol, the puncture strength remains unchanged. The addition of 30% glycerol to HPMC films is also verified at other places in the document (see, for example, table 2, figure 3)</p> <p>It must therefore be assumed that a person skilled in the art is clearly prompted by D5 to use glycerol as a plasticizer and in amounts greater</p>

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
	<p>than 20%.</p> <p>An inventive step under PCT Article 33(3) therefore cannot be recognized for the subject matter of claims 1 to 15.</p> <p>5. Clarity (PCT Article 6)</p> <p>It appears that claim 1 relates to 20% by weight of glycerol, and claim 2, which is dependent on claim 1, relates to 20 to 60% by weight of glycerol.</p> <p>The scope of protection of claim 2 is therefore broader than that of claim 1. It seems appropriate to reverse the order of the claims so that the narrower claim is dependent on the broader claim.</p>

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: **Box I**

The amendments submitted with the letter of 12 September 2005 cannot be considered obvious errors within the meaning of PCT Rule 91. It is not obvious or immediately discernible to a person skilled in the art that nothing else other than the proposed rectifications could have been intended. Another range, such as 20-70%, could also have been intended.

The proposed rectifications are therefore considered to be modifications within the meaning of PCT Article 34(2b) which go beyond the disclosure in the international application as filed because there is no basis in the application documents for the modification to **≥20% by weight**.

This report is therefore based on the originally submitted documents (claims and description).